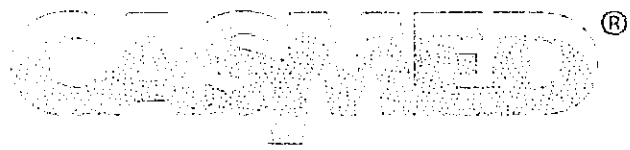
K073036



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
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Prepared:	February 1, 2008
Trade Name:	FORE-SIGHT® Cerebral Oximeter Monitor
Common Name:	Model MC-2000 Series
Classification Name:	Cerebral Oximeter (870.2700)

EQUIVALENCE (Predicate Device)

The FORE-SIGHT® Cerebral Oximeter Monitor, Model MC-2000 is equivalent to the following devices:

- CAS Adult Cerebral Oximeter Model 2040 (K051257)
- Somanetics INVOS® 5100 / 3100A Cerebral Oximeter (K001842 / K960614);
- Spectros T-Stat™ 303 Microvascular Tissue Oximeter (K040684);
- Nellcor N395/N595 Pulse Oximeter (K991823 / K012891);
- Masimo SET Radical Pulse Oximeter (K031330);

DESCRIPTION

The Cerebral Oximeter Monitor measures cerebral tissue oxygen saturation allowing the clinician to accurately determine absolute levels of brain tissue blood oxygen saturation and brain venous oxygen saturation in the brain. This measurement can be of significant value in numerous acute care (OR, ICU, ER) situations, providing health care professionals with information to guard against neurological injuries due to compromised brain oxygenation, which can occur during many surgical and clinical procedures.

The Cerebral Oximeter Monitor consists of an optical transducer containing a laser light source and photodiode detectors, and a graphic display monitor with user interface. The non-invasive, reflection mode, optical transducer is placed on the forehead of the subject via a disposable sensor attachment to determine cerebral oxygenation. The Cerebral Oximeter Monitor is safe to use, because it is designed to operate as a Class I laser product, the safest FDA laser classification. Additional safety features include a laser interlock system designed to prevent laser operation in case the optical transducer is not securely attached to the subject. A patent-protected algorithm optimizes accuracy of the device for measurements of absolute cerebral tissue oxygen saturation..

Cerebral Oximeter Monitor Intended Use

The non-invasive FORE-SIGHT® Cerebral Oximeter Monitor, Model MC-2040 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain. When used with FORE-SIGHT Large sensors, the Cerebral Oximeter Monitor is indicated for use with adults and children over 40 Kg. When used with FORE-SIGHT Small sensors, the Cerebral Oximeter Monitor is indicated for infants and neonates 2.5 Kg. and above. The Cerebral Oximeter Monitor should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the Cerebral Oximeter Monitor has not been demonstrated in disease states.

Cerebral Oximeter Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Cerebral Oximeter Monitor compares substantially to one or more of the cited predicate devices in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All cited monitors use light to probe a cross-section tissue microvasculature. (mixed bed of arterioles, capillaries and venules). The Cerebral Oximeter Monitor and predicate devices analyze light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled

region. All cited monitors calculate oxygen saturation. This value reflects the percentage of oxygenated hemoglobin in the sampled tissue.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The Cerebral Oximeter Monitor has been tested to the following standards in accordance with CAS Medical Systems Product Performance Specifications. The following non-clinical tests have been performed:

- UL 60601-1 Safety testing for use of the UL Classified mark;
- CAN/CSA C22.2 No. 601.1-M90
- IEC 60601-1 Safety of Medical Electrical Equipment;
- EN 60601-1 Safety of Medical Electrical Equipment;
- IEC 60601-1-1 Safety of Medical Electrical Systems;
- IEC 60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC 60601-1-4 Safety of Programmable Electrical Medical Systems;
- IEC 60601-1-8 Safety of Alarm Systems for Medical Equipment/Systems;
- IEC 60825-1: Safety of Laser Products (with amendments A1 and A2);

In addition to the above laboratory tests, CAS has conducted a full program of 22 individual hardware, software and systems monitor and sensor verification and validation studies.

Clinical Testing to Show Substantial Equivalence

Adult Subject Validation: Clinical data on adult subjects was collected at the Duke University Medical Center in Durham, North Carolina. In this study, healthy adult volunteers were subjects for comparison using an internal jugular bulb catheter on the subject's right side and a radial arterial line on the left. Two sensors from the FORE-SIGHT Cerebral Oximeter Monitor were placed bilaterally on the patient's forehead. Hypoxic mixtures of gas were delivered and data was collected in 5 minute intervals during periods of ascending and descending concentrations. At each data collection point, blood samples were drawn simultaneously from the jugular bulb and the radial arterial catheters and analyzed for hemoglobin oxygen saturation using a co-oximeter. The patient was monitored and the protocol stopped if SpO_2 values from a pulse oximeter reached 70%.

Infant & Neonate Subject Validation: 2030 hours of clinical data was collected at the Children's National Medical Center in Washington, DC, and the Children's Hospital of Atlanta (CHOA), Emory University, Atlanta, GA, from subjects undergoing veno-venous Extracorporeal Membrane Oxygenation (VV-ECMO) with cephalad catheterization. In this study, cerebral venous oxygen saturation ($SjvO_2$) measured from blood samples obtained from the internal jugular vein via the cephalad catheter, along with pulse oximetry arterial oxygen saturation (SaO_2) data, were recorded from VV-ECMO neonates without alteration to patient care or blood oxygenation levels while being monitored by the FORE-SIGHT Cerebral Oximeter Monitor over a period of several days for each subject.

Conclusions Drawn from Clinical and Non-Clinical Testing

The data is presented as Root Mean Squared Error (RSME = $\sqrt{(bias^2 + precision^2)}$) for each measured parameter to determine the accuracy of the monitor. RSME accounts for errors relating to both the bias and precision (1 standard deviation) in calculating accuracy. Note that RSME values are approximately equal to the precision or one standard deviation when the bias is small.

Adult $SctO_2$: Using the FORE-SIGHT Large sensor, the Cerebral Oximeter $SctO_2$ showed a strong correlation with the reference $SctO_2$ over the spectrum of values between 45 to 95%. The RSME for the Cerebral Oximeter Monitor $SctO_2$ compared to reference $SctO_2$ derived from co-oximetry of arterial (SaO_2) and jugular bulb ($SjvO_2$) blood samples was ± 3.70 %, based on Equation 1 below.

Infant & Neonate $SctO_2$: Using the FORE-SIGHT Small sensor, the Cerebral Oximeter $SctO_2$ showed strong agreement with the reference $SctO_2$ over the spectrum of values between 50 to 95%. The RSME (1 standard deviation) for the Cerebral Oximeter Monitor $SctO_2$ compared to the reference $SctO_2$ derived from pulse oximetry measured arterial oxygen saturation SaO_2 and co-oximetry measured internal jugular vein venous oxygen saturation ($SjvO_2$) from blood samples was ± 4.77 %, based on Equation 1.

$$Reference\ SctO_2\% = SaO_2 \times 0.3 + SjvO_2 \times 0.7 \qquad Equation\ 1$$

The Cerebral Oximeter Monitor $SctO_2$ value represents oxygen saturation in the brain tissue microvasculature containing venous and arterial blood volume at a ratio of 70:30.

Adult SvO_2: Using the FORE-SIGHT Large sensor, the Cerebral Oximeter SvO_2 showed a strong correlation with the reference $SjvO_2$ over the spectrum of values between 35 to 90%. The RSME for the Cerebral Oximeter Monitor SvO_2 compared to reference $SjvO_2$, derived from co-oximetry of the jugular bulb blood samples was ± 5.26 %. SvO_2 was determined from Equation 2 below.

$$SvO_2 = (SctO_2 - SaO_2 \times 0.3) / 0.7 \qquad Equation\ 2$$

In the above expression, SaO_2 is arterial oxygen saturation from a pulse oximeter and $SctO_2$ is determined by the FORE-SIGHT Cerebral Oximeter Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CAS Medical Systems, Inc.
% Mr. Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Road
Branford, Connecticut 06405

FEB 25 2008

Re: K073036
Trade/Device Name: FORE-SIGHT® Cerebral Oximeter Monitor, Model MC 2000 Series
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 4, 2008
Received: February 6, 2008

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073036

Device Name: **FORE-SIGHT® Cerebral Oximeter, Model MC-2000 Series**

Indications for Use: The non-invasive FORE-SIGHT Cerebral Oximeter Model MC-2000 should be used as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain. When used with FORE-SIGHT large sensors, the Cerebral Oximeter Monitor is indicated for use with adults and children over 40Kg. When used with FORE-SIGHT small sensors, the Cerebral Oximeter Monitor is indicated for infants and neonates 2.5Kg and above. The Cerebral Oximeter Monitor System should not be used as the sole basis for decisions as to the diagnosis or therapy. The value of data from the oximeter has not been demonstrated in disease states.

Prescription Use √ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073036